

## REMARKS

Attached hereto is a marked-up version of the changes made to the claims by the above amendment. The attached page is captioned “**Version with markings to show changes made.**”

Claim 12 has been amended to emphasize the inherent nature of the subject matter of the claim as relating to a “Schiff base of a *primary amide of an amino acid*” (emphasis added). The amendment is supported by the instant application and claims as originally filed, and no new matter has been introduced. Entry is respectfully requested.

### *Prior art rejection under 35 U.S.C. § 103*

Claims 12-22 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Hijiya et al. Applicants have carefully reviewed the statement of the instant rejection as well as the cited reference and respectfully traverse the rejection as failing to have presented a *prima facie* case of obviousness.

As an initial matter, Applicants again point out that there is no teaching, suggestion or indication in Hijiya et al. of racemization of a Schiff base of a **primary amide** of an amino acid. The statement of the rejection appears to acknowledge this fact (see page 3, third paragraph, of the instant Action). In the absence of such a teaching, suggestion, or indication, no *prima facie* case of obviousness is present because not all limitations of the claimed invention are disclosed by Hijiya et al. as required by MPEP 2143.03 and the cases cited therein.

While Applicants note the assertion that Hijiya et al. refer “to racemization of an amide(may not be primary amide)”, Applicants respectfully point out that the only amide disclosed by Hijiya et al. is a **secondary** amide referred to as “amino acid-N-(S)- $\alpha$ -alkylbenzylamide”. The structure of this secondary amide is found in each of formulas 1, 2 and 3 disclosed by Hijiya et al. As such, Applicants respectfully submit that contrary to the assertion, Hijiya et al. **do not** teach or suggest the racemization of amides in general and similarly **do not** teach or suggest the racemization of a primary amide.

To the contrary, the teachings of Hijiya et al. are limited to one species (a secondary amide) while the instant invention is directed to a different species (a primary amide). In the absence of a teaching or suggestion to go from one species to another, there is simply no motivation to modify the teachings of Hijiya et al., limited to a single secondary amide, to arrive

at the claimed invention, directed to a **primary** amide. As the Examiner will no doubt appreciate, such motivation is required as set forth at MPEP 2143.01 and the cases cited therein.

Additionally, Applicants note that there is no indication in the instant rejection of why an artisan of ordinary skill would expect that a **primary** amide of an amino acid would function equivalently in the teachings of Hijiya et al. To the contrary, and as discussed in the previous Reply of April 29, 2002 (mailed April 19, 2002), Hijiya et al. specifically utilize a **secondary** amide because of the presence of a chiral center in the amine used to form the **secondary** amide. The resulting secondary amide of an amino acid would thus have two chiral centers (one at the amino acid's alpha carbon and the second from the amine) which permits the formation of two diastereomers (with different properties) upon racemization at the amino acid's alpha carbon chiral center. Hijiya et al. then specifically teaches the specific isolation of the diastereomer corresponding to the D-amino acid. See column 2, lines 6-33.

The above teachings of Hijiya et al. cannot be performed by preparation of a primary amide in place of the secondary amide because the resulting primary amide of an amino acid would only have a single chiral center at the alpha carbon. Racemization at that center would create two enantiomers that cannot be separated by the method disclosed in Hijiya et al. Therefore, Applicants respectfully submit that there is **no** expectation of success in the asserted modification of Hijiya et al. to utilize a primary amide (see the basis of the requirement at MPEP 2143.02 and the cases cited therein). To the contrary, there is evidence that the teachings of Hijiya et al. would lead the artisan of ordinary skill *away from* the use of a primary amide and toward the use of a secondary or tertiary amide because only secondary or tertiary amides can introduce a second chiral center into the resulting amide.

As for any assertion concerning the same base, same amount of base, and/or same mechanism between the instantly claimed invention and Hijiya et al., Applicants respectfully point out that the disclosure of Hijiya et al. is limited to reactions with a **secondary** amide. Therefore, similarities to reactions with a **primary** amide are irrelevant where, as in the instant case, use of a **primary** amide is not obvious. This was the point of the comments made in the previous Reply of April 29, 2002 (mailed April 19, 2002).

Finally, and to the extent that the instant rejection may be based upon some concept of "inherent obviousness" of transforming the teachings of Hijiya et al. to be within the scope of the

present claims, Applicants respectfully point out that there is no legal basis for such a concept in U.S. patent law.

In light of the above, Applicants respectfully submit that there is insufficient support to establish a *prima facie* case of obviousness in the instant rejection. Accordingly, withdrawal of the instant rejection is respectfully requested.

### CONCLUSION


Applicants believe pending claims 12-22 are in a position for allowance and passage of these claims to issue is respectfully requested. The Examiner is encouraged to contact the undersigned if she determines that further discussions would prove useful.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 246152014800.

Respectfully submitted,

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By: \_\_\_\_\_

  
Kawai Lau, Ph.D.  
Registration No. 44,461

Morrison & Foerster LLP  
3811 Valley Centre Drive,  
Suite 500  
San Diego, California 92130-2332  
Telephone: (858) 720-5178  
Facsimile: (858) 720-5125

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

**Please amend claim 12 as follows:**

12. (Twice Amended) A process for racemising an enantiomer-enriched Schiff base of a primary amide of an amino acid which process comprises contacting said enantiomer-enriched Schiff base of a primary amide of an amino acid with a strong base in an organic solvent,  
wherein said strong base is chemically reactive with water.